

Attorney Docket: Beiersdorf 754

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

REMARKS

Claims 10 to 20 were pending.

Claim 10 was further amended to clarify the function and the content of the "active ingredient component" in the claimed composition.

It is believed that no amendment introduces new matter.

Written Description

Applicants respectfully disagree with Examiner's rationale underlying the conclusion that the specification would not support a composition comprising the combination of components (a) and (b) in claim 10 as the sole active ingredient component. The specification clearly states that the combination of (a) and (b) may be viewed as the "active ingredient used according to the invention," or the "active ingredient combination." Page 9, 3rd ¶. Further, by alternatively describing the combination as "active ingredients..." it is clear that the Applicants have expressly made a distinction in defining their invention wherein the combination of (a) and (b) is one of at least one active ingredient component.

In supporting this rejection, Examiner states that the specification "nowhere conveys that (a) and (b) are the only active ingredients." In view of the above cited text this conclusion is inaccurate.

Attorney Docket: Beiersdorf 754

Examiner then asserts that there are no embodiments in which (a) and (b) are the only active ingredients. Respectfully, this conclusion is improperly premised on interpreting the term "active ingredients" as being equivalent to "any ingredients." In other words, Examiner confers *active ingredient* status to any or all ingredients listed in the exemplified embodiments.

It is likely that Examiner's attributes active status to all ingredients because the basis of the combination's role has not been sufficiently described in the claim. In other words, claim 10 lacks specific language referring to an activity that is descriptive of the combination's properties that results in it being an *active* combination.

In response, claim 10 has been amended to functionally define the activity or property that renders (a) and (b) an active ingredient combination. Specifically, the claim now reflects the fact that this combination has been found to impart enhanced or improved stability to the chemical constituents of the composition. See page 3, lines 7-19. The prolonged maintenance of the composition would have significant effect on the shelf-life and the economics of manufacturing compositions that include the active combination as claimed.

The Applicants assert that the combination of (a) and (b) provides act synergistically in providing the enhanced stability that was previously unforeseeable. It is implicit in this disclosure that α -lipoic acid is found to function in a superior manner as component (b) than other antioxidants. Examiner has the burden to provide sufficient reasoning or evidence that would refute the existence of this disclosed synergism.

As cited in the MPEP, [a] description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. MPEP § 2163.

Respectfully, there is no such reasoning or evidence of record to rebut the rule of Marzocchi. Accordingly, the Applicants' disclosure must be taken as true and accurate unless Examiner provides the required level of evidence to challenge it. Absent such reasoning or evidence, it is believed that amended claim 10 should be allowed. I

Attorney Docket: Beiersdorf 754

It is respectfully requested that the new matter rejection be withdrawn, and that the amended claims be allowed.

Obviousness

Amending claim 10 is believed to overcome the rejection over US 518 (English language version of WO 282).

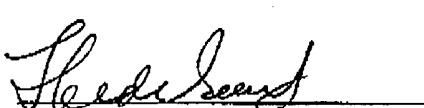
Although the '518 discloses antioxidants, there is no disclosure of the use of antioxidants to stabilize the constituents of the compositions. The '518 deals mainly with formulating low-viscosity compositions and does not disclose any synergistic or unexpectedly superior result that would result from employing α -lipoic acid as the sole component of (b).

The conceptual basis of this empirical observation is not known, but was established empirically. What is critical to maintaining this rejection is US '518 does not provide any guidance that would have provided to persons of ordinary skill in the art, a reasonable expectation of success in using US 518 to arrive at the synergistic combination of (a) and (b).

On this basis, the rejection should be withdrawn.

Respectfully Submitted,

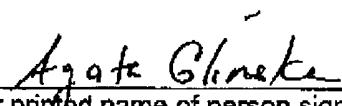
Norris, McLaughlin & Marcus
220 East 42nd Street
New York, NY 10017
Telephone (212) 808-0700
Facsimile (212) 808-0844


Theodore Gottlieb, PhD
Reg. No. 42, 597

Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office Fax No. (703) ~~872-9306~~

on June 24, 2004
(Date)


Typed or printed name of person signing this certificate

Signature Agata Glinska